



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,994	12/03/2003	Kedar R. Belhe	47563.0015	4512
57600 7590 03/28/2007 HOLLAND & HART LLP 60 E. SOUTH TEMPLE SUITE 2000 SALT LAKE CITY, UT 84111			EXAMINER WOO, JULIAN W	
			ART UNIT 3731	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		.03/28/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/726,994

Applicant(s)

BELHE ET AL.

Examiner

Julian W. Woo

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 21-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 21-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/18/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 1, line 4, the first and second needles, which are parts of the vascular closure device, are said to be "coupled to the vascular device." How can an integral part of the device be coupled to itself? In claim 1, lines 13 and 14, "the opening" lacks antecedent basis. Also with respect to claim 3, the first and second needles are said to "extend outward and away from the vascular device." How can an integral part of the device extend outward and away from itself?

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 3731

4. Claims 1, 3-7, 11, 13-18, and 21-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Modesitt et al. (6,136,010). Modesitt et al. disclose, at least in figures 4-5, 11A-11E, and 13 and in col. 10, line 18 to col. 11, line 29; a vascular closure device and a method with the device for closing a vascular opening; where the device includes first and second needles (38, 38'), a suture (34), a snare (42 and/or 40 and 74), a pre-tied knot (80), and a handle (20), where the first and second needles extend outward and away from a sheath (12) at an angle of 3 deg. to 20 deg.; where the method includes inserting a sheath or sleeve (12) into a vessel, inserting a snare (42 and/or 40 and 74) and a needle (38) on a first side of a vessel opening, inserting a suture (34) and another needle (38') on a second side of the opening, grasping the suture with the snare, pulling the suture across the vessel opening (see fig. 11d), directing the distal end of the suture through a pre-tied knot (80) at a proximal end of the suture, cinching the knot or tightening the suture, disengaging and withdrawing the sheath (12) from the vessel opening; where the device is secured in the blood vessel (via 24), where the sheath is anchored in the vessel with a pair of extendable feet (24a and 24b or 22 and 24), and where a safety wire (GW) can be inserted into the vessel opening and be used to facilitate reinsertion of the sheath.

5. Claims 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Riza (5,562,688). Riza discloses, at least in figure 5 and in col. 7, line 37 to col. 8, line 54; a vascular closure device including a snare (80) configured to be inserted through a wall of a blood vessel at a location adjacent to an opening in the blood vessel, and a suture (81) configured to be inserted through the wall of the blood vessel at another location

adjacent the opening, where the snare comprises a loop (84) having a memory, where the snare and the suture each move between retracted and extended positions, and where the device includes a handle (proximal portion of 80).

6. Claims 7 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Burbank et al. (6,638,286). Burbank et al. disclose, at least in figures 7-24 and in col. 6 line 53 to col. 7, line 44 and col. 9, line 49 to col. 10, line 60; a vascular closure device including a snare (126) configured to be inserted through a wall of a blood vessel at a location adjacent to an opening in the blood vessel, a suture (154) configured to be inserted through the wall of the blood vessel at another location adjacent the opening, and first and second needles (120, 122).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 3731

8. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riza (5,562,688) in view of Goldrath (5,330,488), and further in view of Kammerer (5,562,684). Riza discloses the invention substantially as claimed. Riza discloses, at least in figure 5, a device including a needle movable between retracted and extended positions with respect to a tubular housing (11), a suture (81), and a snare (84) configured to move with the needle, where the snare comprises a wire loop (84) having a memory as claimed. However, Riza does not disclose another needle configured to be movable between retracted and extended positions with respect to the tubular housing (11) and a suture movable with another needle between retracted and extended positions, where the suture proximal end includes a pre-tied knot. Nevertheless, Riza discloses, in col. 8, lines 25-28, that elongated tools may be inserted into the tubular housing for manipulation of suture. Goldrath teaches, at least in figures 2 and 6, an elongated tool or needle (40) for manipulation of suture. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Goldrath, to apply a needle for carrying and manipulation of a suture in the Riza's device. Such a needle would allow the guidance of suture into relatively inaccessible or closed surgical sites, where a suturing procedure can further be more performed with the use of a snare as disclosed by Riza (and as also taught by Goldrath). Moreover, Kammerer teaches, at least in figures 16-25 a suture (100) with a pre-tied knot (102) on its proximal end. It also would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kammerer, to include a pre-tied knot with the suture of Riza's device. Such a knot would allow a quick

Art Unit: 3731

and convenient means for tying and tightening a suture around tissues to be joined together.

Response to Amendment


9. Applicant's arguments with respect to claims 1-18 and 21-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Julian W. Woo
Primary Examiner

March 24, 2007